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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,635	05/18/2000	OLIVIER BALLEVRE	P00.0164	7617

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BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/508,635	Applicant(s) BALLEVRE ET AL.	
	Examiner David Lukton	Art Unit 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *30,32,35 and 37-41*.
   Claim(s) withdrawn from consideration: *33 and 34*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheets.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Advisory Action

Claims 30, 32-35 and 37-41 remain pending. Claims 33-34 remain withdrawn from consideration.

The amendment filed 7/8/05 directs the amendment of claim 30. However, this amendment will not be entered. First, the proposed amendment to claim 30 introduces new matter. There is no line of demarcation in the specification between internal organs and external organs. In addition, there is no description of "internal administration". It is true that on page 9, lines 6-7, the following passage is recited:

> "The nutritional formula may also be administered continuously by means of nasogastric tubes or enteral tubes...".

However, this does not provide support for "internal administration", or even parenteral administration. Nor is it clear, even at this point, what exactly is encompassed by "internal administration", or why it is that applicants believe that food which passes through the esophagus is somehow not present "internally".

And even if the amendments to claim 30 did not constitute new matter, they would not be entered, since the amendment raises new issues that would require further consideration and search.

✦

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As indicated previously, the specification fails to teach a skilled physiologist how to use protein hydrolyzates and amino acids to promote "recovery" of an organ. The term at issue ("recovery") encompasses treatment of Crohn's disease, diarrhea, colitis and sepsis (page 8, line 20+, specification). The term at issue also encompasses accelerated healing of gut epithelial tissue that has resulted from a surgical procedure, or from any other cause. In the arguments presented (response, 7/8/05), applicants have not attempted to address these specific disorders/injuries, but instead have offered general comments. It is suggested that applicants point out the exact location in the specification where it is disclosed that if one of the subject protein hydrolyzates is administered to a mammal afflicted with Crohn's disease, diarrhea, colitis or sepsis, therapeutic relief occurs as a consequence of the administration. This will help to advance the discussion. Absent such evidence, it will remain the case that the specification fails to teach a skilled physiologist how to use

protein hydrolyzates and amino acids to promote "recovery" of an organ, at least without the expenditure of "undue experimentation".

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of promoting "recovery" of an organ. It is unclear as to what the organ is recovering from. The the term could potentially encompass recovery from a wound, physical trauma, or a disease. Despite the amendment, the line between what is encompassed and what is not encompassed remains unclear. For example, one organ is the brain. Is "recovery" from a headache encompassed, or recovery from emotional stress, or recovery from excessive alcohol consumption? It is suggested that the claim be amended to make clear what the mammal is recovering from.

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C.

102(f) or (g) prior art under 35 U.S.C. 103.

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Nakamura (*J. Dairy Sci.* **78** (6) 1253-1257, 1995) or Masuda (*American Institute of Nutrition* **126**(12) 3063-3068, 1996).

As indicated previously, Nakamura discloses that peptides obtained from sour milk exhibit antihypertensive activity. Nakamura does not disclose that antihypertensive agents will promote "recovery" of a damaged heart in hypertensive patients. Masuda provides a similar teaching. Applicants have argued that neither reference discloses that antihypertensive agents are often prescribed for hypertensive patients how have suffered a heart attack. However, this is well known in the art. The rejection is maintained.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132) or Tomita (USP 5,313,873).

As indicated previously, Gordon and Tomita both teach that milk protein hydrolyzates can be used to treat skin. Neither reference uses the phrase "recovery of an organ". However, the skin is an organ of sorts, and if the hydrolyzates are indeed effective to relieve dermatological conditions such as dermatitis, burns and bruises, then this would correspond to "recovery of an organ".

Applicants have argued that, if the amendment to claim 30 (filed 7/8/05) were to be entered, it would overcome this ground of rejection. While applicants may be correct

about this, the point is moot, since the amendment is not being entered at this time.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gordon (USP 5,166,132) or Tomita (USP 5,313,873) in view of Verma (USP 6,645,942). The teachings of Gordon and Tomita are indicated above. Neither reference discloses that skin is an organ. Verma discloses (col 4, line 47) that skin is an organ. Verma does not disclose the use of milk protein hydrolyzates to promote recovery of an organ.

The rejection is maintained, since the amendment has not been entered.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Smith (WO 97/16460).

As indicated previously, Smith discloses that a casein hydrolyzate has growth promoting activity. Smith does not explicitly state that the casein hydrolyzate will promote "recovery of an organ". However, one of ordinary skill would expect that growth of organs will be promoted, those of infants, as well as those of adults who have suffered damage to an organ as a result of disease, injury or surgical procedure.

In response to the foregoing, applicants have argued that because Smith has identified growth factors within the milk protein hydrolyzates, the disclosed hydrolyzates do not qualify as a "specific milk protein hydrolyzate". However, the peptides and mixtures

disclosed in Smith do qualify as "specific milk protein hydrolyzates", since they are both hydrolyzates, and specific.

Applicants have argued that Smith does not disclose that varying the degree of hydrolysis has the effect of varying the degree of absorption. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Jolles (USP 4,716,151).

As indicated previously, Jolles discloses that tripeptides obtained from hydrolysis of milk proteins will stimulate the immune system. Jolles does not disclose that the recited tripeptides will promote recovery of an organ in an immune compromised patient.

Applicants have argued that the immunostimulatory effect is general, and not specific. This particular point may be correct, but what matters is what is encompassed by the prior invention. It may be the case that the peptides of Jolles will exhibit effects in addition to promoting recovery of infected organs (infected by bacteria, viruses or fungi). But as long as one of those effects is encompassed by the instant claims, the requirements of the claims are met, as is the case here.

The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Ballard (USP 5,679,771) in view of Stalker (USP 5,661,123).

Ballard discloses (e.g., col 2, line 6+; col 2, line 26+; col 1, line 30+) recovery from Crohn's disease and colitis, and recovery from surgical procedures by administering IGF-1 and analogs thereof. Ballard does not disclose a method of promoting recovery by administering hydrolyzed milk proteins. Stalker discloses (col 3, line 50) administration of hydrolyzed milk proteins to patients who have "elevated protein requirements". Stalker further discloses (e.g., col 3, line 40; col 5, line 47) that persons afflicted with Crohn's disease have "elevated protein requirements" and would benefit from the hydrolyzed milk proteins. While disclosing that persons suffering from Crohn's disease would benefit from the hydrolyzed milk proteins, Stalker stops short of asserting that the inflammation associated with the Crohn's disease will actually be mitigated.

In response to the foregoing, applicants have argued that neither reference taken alone forms the basis for a proper rejection under 35 USC §102. This particular point is conceded. Next, applicants have argued that Stalker fails to teach that persons afflicted with Crohn's disease will benefit from the protein hydrolyzates. However, applicants are not correct. This is disclosed, e.g., at col 3, line 40 and col 5, line 47.

Applicants have also argued that Stalker does not disclose that varying the degree of

hydrolysis has the effect of altering the extent to which benefit accrues to specific organs While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Qu, Zhensheng (*Journal of Nutrition* **126**(4) 906-912, 1996) in view of Stalker (USP 5,661,123).

Qu discloses that protein malnutrition is manifest in various ways both biochemically and physiologically; one of those manifestations is suboptimal liver growth. Qu further discloses that the deficiency in liver growth which accompanies protein malnutrition can be reversed by administering proteins, such as casein; in other words, proteins promote "recovery" of the liver from protein malnutrition. Qu does not disclose that hydrolyzed milk proteins can serve as a protein source.

Applicants have argued that Stalker does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein.

In response, applicants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Van Leeuwen (USP 6,001,878).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein. The reference also suggests (col 3, line 47; col 5, line 56) administration of glutamine in addition to the hydrolyzed milk protein. Gray does not disclose that glutamine will promote recovery of an organ. Van Leeuwen discloses that glutamine will promote recovery of the liver. Van Leeuwen does not disclose

administration of hydrolyzed milk proteins.

In response, applicants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✧

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Gray (USP 5,723,446) in view of Panigrahi (USP 5,981,590).

Gray discloses (col 2, line 57+) a method of treating patients suffering from burns, and from surgical procedures. The method calls (col 3, line 27) for administration of hydrolyzed milk protein. The reference also suggests (col 3, line 47; col 5, line 56) administration of glutamine in addition to the hydrolyzed milk protein. Gray does not disclose that glutamine will promote recovery of an organ. Panigrahi discloses that glutamine will promote recovery of the intestines. Panigrahi does not disclose administration of hydrolyzed milk proteins.

In response, applicants have argued that Gray does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the

improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

Claims 30, 32, 35 and 37-41 are rejected under 35 U.S.C. §103 as being unpatentable over Boza, Julio (*Journal of Pediatric Gastroenterology and Nutrition* **22**(2) 186-193, 1996).

Boza discloses that the weight and protein content of the jejunum mucosa is reduced following starvation, and that the hydrolase activity of the mucosa also is also reduced in starvation. Boza also discloses that these effects of starvation are reversed following administration of hydrolyzed milk proteins. Boza does not disclose that administration of hydrolyzed milk proteins will promote recovery of an organ.

In response, applicants have argued that Boza does not disclose that varying the degree of hydrolysis has the effect of altering the extent to which benefit accrues to one specific organ versus another. While applicants may be correct on this point, the claims are not drawn to a method of varying the degree of hydrolysis, or a Jepson claim in which the improvement is varying the degree of hydrolysis. The rejection is maintained.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1800